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APPLICATION NO. ATTORNEY DOCKET NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. 10/046,540 01/16/2002 Gavriel J. Iddan P-2752-US 1800 27130 7590 03/18/2004 **EXAMINER** EITAN, PEARL, LATZER & COHEN ZEDEK LLP FOREMAN, JONATHAN M 10 ROCKEFELLER PLAZA, SUITE 1001 ART UNIT PAPER NUMBER NEW YORK, NY 10020 3736 DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	L Amelia and a
Office Action Summary	Application No.	Applicant(s)
	10/046,540	IDDAN, GAVRIEL J.
	Examiner	Art Unit
	Jonathan ML Foreman	3736
The MAILING DATE of this communication app Period for Reply	bears on the cover sheet with	the correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	36(a). In no event, however, may a rep y within the statutory minimum of thirty (will apply and will expire SIX (6) MONTh , cause the application to become ABA	ly be timely filed 30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).
1) Responsive to communication(s) filed on 15	<u>December 2003</u> .	
2a) This action is FINAL . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims 4)⊠ Claim(s) <u>1-47</u> is/are pending in the application	, ·	
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-47</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers	· · · · · · · · · · · · · · · · · · ·	
9) The specification is objected to by the Examine	er.	
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.		
If approved, corrected drawings are required in reply to this Office action.		
12)☐ The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. §§ 119 and 120		
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
a) ☐ All b) ☐ Some * c) ☐ None of:		
1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No		
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).		
 a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 		
Attachment(s)		
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 	5) Notice of In	ummary (PTO-413) Paper No(s) formal Patent Application (PTO-152)
S. Patent and Trademark Office		

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DETAILED ACTION

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 8/15/03. Accordingly, the following action has been made Non-Final.

Information Disclosure Statement

The information disclosure statement filed 3/1/04 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits. However, JP 4-109927 and WO 99/11754 have been lined-through because they are already of record.

Drawings

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 12/15/03 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1 3, 5, 6, 15, 22, 27, 28 and 43 46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,330,464 to Colvin, Jr. et al.

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In reference to claims 1 – 3, 5, 6, 15, 22, 27, 28 and 43 – 46, Colvin, Jr. et al. discloses an autonomous device configured for being capable of passing through a body lumen having at least one interaction chamber (14', 14") for containing a sample while in vivo (Col. 25, lines 51 – 61), the chamber having at least one indicator therein for reacting with the sample for generating optical changers in the chamber; at least one illumination source (18) for illuminating the chamber; and at least one optical detector (20-1, 20-2) for detecting optical changes occurring in the chamber (Col. 6, lines 26 – 56). The chamber is transparent in the wavelength of illumination. Colvin, Jr. et al. discloses a plurality of chambers each having a indicator separate from one another (Col. 12, line 65 – Col. 13, line 2). Each chamber is sealed by a membrane which selectively enables passage of a sample but not of the indicator (Col. 6, lines 51 – 56). Colvin, Jr. et al. discloses receiving an endoluminal sample in an interaction chamber, the chamber having at least one indicator therein for reacting with the endo-luminal sample for generating optical changes in the chamber; illuminating the chamber; and detecting the optical changes occurring in the chamber (Col. 6, lines 26 – 56). Colvin, Jr. et al. discloses a transmitter.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 4 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,330,464 to Colvin, Jr. et al. as applied to claims 1 and 43 above, and further in view of U.S. Patent No. 4,817,632 to Schramm.

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In regards to claims 4 and 47, Colvin, Jr. et al. discloses obtaining a sample in the interaction chamber using a selectively permeable membrane (Col. 6, lines 51 - 56), but fails to disclose using a micro pump for drawing the sample. Schramm discloses a device for collecting a sample in a chamber using a selectively permeable membrane. Schramm discloses the use of a micro pump to aid in the movement of the sample across the membrane to the chamber (Col. 4, lines 19 - 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as disclosed by Colvin, Jr. et al. to include a micro pump as taught by Schramm in order to draw the sample into the interaction chamber for analysis (Col. 3, lines 35 - 44).

6. Claims 1 - 2, 7 – 18, 21 – 38 and 40 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/53792 A2 to Given Imaging Ltd. In view of U.S. Patent No. 6,330,464 to Colvin, Jr. et al.

In regards to claims 1 – 2, 7 – 18, 21 – 38 and 40 – 46, Given Imaging Ltd. Discloses an autonomous device capable of passing through a body lumen and determining in vivo conditions, the device having at least one interaction surface (54) for receiving a sample while in vivo, the surface having at least one indicator immobilized thereon for reacting with the sample for generating optical changes (Page 6, lines 14 – 19); at least one illumination source (51) for illuminating the surface; and at least one optical detector (55) for detecting optical changes occurring on the surface. The surface is transparent in the wavelength of illumination (Page 11, line 30). Given Imaging Ltd. discloses the optical detector being an imager for obtaining images of the interaction surface and of the body lumen in which the device is disposed and producing video signals thereof (Page 11, line 29 – Page 12, line 3). The device includes a transmitter for transmitting the video signals and a receiving system for receiving the video signals (Page 11, line 26). Given Imaging Ltd. discloses the device being suitable for passing through a GI tract and receiving a sample from the GI

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environment (Page 11, line 32 – Page 12, line 2). Given Imaging Ltd. discloses the device being a swallowable capsule. However, Given Imaging Ltd fails to disclose the interaction surface being an interaction chamber. Colvin, Jr. et al. discloses an autonomous device for determining in vivo condition. Colvin, Jr. et al. teaches the device having an indicator located within an interaction chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the interaction surface as disclosed by Given Imaging Ltd. to include an interaction chamber containing the indicator as taught by Colvin, Jr. et al. in order to help protect the indictor while in use (Col. 25, lines 50 – 61)

7. Claims 19, 20, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,330,464 to Colvin, Jr. et al. in view of WO 01/53792 A2 to Given Imaging Ltd.

In regards to claims 19, 20, 38 and 39, Colvin, Jr. et al. discloses a system for determining in vivo conditions, the system having two opposing ends; two interaction chambers (14', 14") for containing a sample while in vivo, the chambers each having at least one indicator therein for reacting with the sample for generating optical changes in the two chambers (Col. 12, line 65 – Col. 13, line 2); at least one illumination source (18) for illuminating the two chambers; two sensors (20-1, 20-2) for detecting optical changes occurring in the interaction chambers and producing signals thereof, a transmitter for transmitting the signals to a receiving system, wherein the two chambers and sensors are positioned at an opposing end of the system. Colvin, Jr. et al. discloses a battery (40) for providing power to the system. However, Colvin, Jr. et al. fails to disclose the sensors being image sensors for obtaining in vivo images of the interaction chambers and the surrounding environment. Given Imaging Ltd. discloses a system for determining in vivo conditions where the sensor can be an optical detector or an image sensor for detecting optical changes and for obtaining in vivo images of the interaction surfaces and the surrounding environment (Page 6, line 30 – Page

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7, line 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the optical sensors as disclosed by Colvin, Jr. et al. to be an image sensor as taught by Given Imaging Ltd. in that Given Imaging Ltd. teaches the optical sensor and the image sensor as functionally equivalent and therefore interchangeable.

Response to Arguments

- 8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.
- 9. However, the Examiner agrees with the Applicant in view of the rejections made in the Office Action dated 8/15/03. Specifically, the 35 USC § 112 rejection has been withdrawn because the claim now is definite. Additionally, the 35 USC § 102 and 35 USC § 103 rejections have been withdrawn because the claims now clearly recite limitations related to the autonomous structure of the device; a feature the prior art previously made of record does not teach or suggest.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703)308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

March 8, 2004

May Bet Gres Acting SPE AU 3736